INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

REQUIREMENTS FOR THE SUBMISSION OF PHYTOSANITARY TREATMENTS

Secretariat of the International Plant Protection Convention
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
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CONTENTS

INTRODUCTION

SCOPE

This standard describes the criteria for a phytosanitary treatment and the requirements for submitting a proposed phytosanitary treatment for inclusion in the ISPM on phytosanitary treatments [under development].

Treatments considered in this standard are applied to commodities or to regulated articles.

Pesticide registration is the responsibility of each contracting party and is not part of this standard.

REFERENCES

Glossary of phytosanitary terms, 2004. ISPM No. 5, FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.

DEFINITIONS

At its Seventh session in April 2005, the Interim Commission on Phytosanitary Measures adopted recommendations on the publication of ISPMs in a book format (see ICPM-7 report, paragraph 39 and Appendix II). Each book of ISPMs will contain a glossary chapter, i.e. the *Glossary of phytosanitary terms* (ISPM No. 5) in the relevant language.

The "definitions" section in the present ISPM, once integrated into the book, will not contain any definitions but will refer to the Glossary chapter of the book (ISPM No. 5). However, for the purpose of country consultation, this section contains terms or definitions which are new or revised in the present draft standard. Once this standard has been adopted, the new and revised terms and definitions will be transferred into the Glossary chapter of the book (ISPM No. 5), and will not appear in the standard itself.

New term and definition:

treatment schedule	The elements of a treatment that are critical to achieving the stated efficacy. The most critical elements are dose, time and temperature.

OUTLINE OF REQUIREMENTS

Phytosanitary treatments may be required by contracting parties as phytosanitary measures to prevent the spread and introduction of pests of plants and plant products.

Treatments should fulfil certain criteria in relation to their efficacy, feasibility and applicability.

National Plant Protection Organizations (NPPOs) or Regional Plant Protection Organizations (RPPOs) submit a proposed treatment for inclusion in the ISPM on phytosanitary treatments [under development] by providing information on the treatment, pest(s) and commodity(ies) or regulated articles concerned. The submission should include efficacy data on the treatment under laboratory or controlled experimental conditions, and also under practical conditions. The level of efficacy of the treatment should be stated in the submission and should be applicable to use of the treatment internationally. Information on the technical and commercial feasibility of the treatment should be provided.

Submissions will be evaluated by the Technical Panel on Phytosanitary Treatments to determine whether the treatment is of use internationally. Once adopted, phytosanitary treatments will be published in the ISPM on phytosanitary treatments [under development] and in a treatments database on the International Phytosanitary Portal (www.ippc.int).

BACKGROUND

The purpose of the IPPC is "… *to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control* …" (Article I.1 of the IPPC, 1997). One phytosanitary measure used by contracting parties to prevent the introduction and spread of pests is to require or to apply phytosanitary treatments to commodities and regulated articles.

Article VII.1 of the IPPC 1997 states: "*... contracting parties shall have sovereign authority to regulate, in accordance with applicable international agreements, the entry of plants and plant products and other regulated articles and, to this end, may:*

a) *prescribe and adopt phytosanitary measures concerning the importation of plants, plant products and other regulated articles, including, for example, inspection, prohibition on importation, and treatment*."

Phytosanitary measures required by an importing contracting party should be technically justified (Article VII2.a of the IPPC, 1997). The overall aim of the process described in this standard is for data submitted by National Plant Protection Organizations (NPPO) or Regional Plant Protection Organizations (RPPOs) to be evaluated by the Technical Panel on Phytosanitary Treatments for their efficacy, and technical and commercial feasibility. Suitable treatments will be recommended for adoption as international phytosanitary treatments and for inclusion in the ISPM on phytosanitary treatments [under development]. Such treatments may be utilized where appropriate without further technical justification.

Contracting parties should take into account other issues when applying phytosanitary treatments, such as the effects on human health and safety, animal health and the environment (see the preamble and Article I.1 of the IPPC, 1997). Effects on the quality of the commodity should also be considered.

REQUIREMENTS

1. Criteria for Treatments

1.1 General requirements

The following requirements should be met:

- the treatment should be effective in killing, inactivating, or removing of target pests, rendering pests infertile or devitalizing pests associated with the target commodity(ies) or regulated articles.
- the data should be based on statistically sound methods or on established and accepted international practice and, where possible, it should have been published in a peer-reviewed journal.
- the level of efficacy should be stated (quantified or expressed statistically). Where statistical data is unavailable, other evidence that supports the efficacy (i.e. historical and/or practical information/experience) should be provided.
- the way the treatment can be used effectively in practice (e.g. as part of a systems approach) should be stated.
- the treatment should be applicable for use in international trade or other movement, e.g. for research purposes.

1.1.1 Efficacy data from laboratory or controlled experiments

The methods and materials utilized in the experiments should be suitable for the proposed use of the treatment at the stated efficacy. This includes the following:

- identity of pest used in the trials (e.g. strain, biotype, physiological race and life stage, laboratory or field strain), including conditions under which they are cultured/reared
- target commodity/regulated article (e.g. maturity, variety)
- experimental facilities and equipment
- methodology to measure the effectiveness of the treatment (for example, whether mortality is the proper parameter or whether the end-point mortality was assessed at the correct time)
- monitoring of critical parameters (such as dose, temperature, relative humidity).

1.1.2 Efficacy data on the target pest(s) under practical conditions

The proposed treatment developed under laboratory conditions should be validated by testing under practical or simulated practical conditions. Results of these tests should confirm that the application

of the treatment schedule achieves the stated efficacy under conditions in which the treatment will be used.

1.2 Feasibility and applicability

The proposed phytosanitary treatment should be feasible and applicable internationally. Factors that may affect the feasibility and applicability include commercial relevance, technical viability, human health and safety, commodity quality and environmental impact.

Treatment schedules should adequately describe the method for applying the treatment in a commercial environment.

2. Requirements for Submission of a Proposal for a Phytosanitary Treatment

A proposal justifying a phytosanitary treatment for inclusion in the ISPM on phytosanitary treatments should be submitted by an NPPO or RPPO to the IPPC Secretariat according to the requirements in this section. These requirements provide guidance for the submission of data on treatments that have already been developed or for development of new treatments.

2.1 General considerations

The NPPO or RPPO should ensure that the experimental design provides a final proposed phytosanitary treatment with a degree of efficacy appropriate for international use. It is recommended that the results of the research in support of the proposed phytosanitary treatment should be peer reviewed and approved prior to submission by the NPPO or the relevant RPPO.

The data supporting the treatment should be presented clearly and systematically, preferably in accordance with the requirements in the following sections.

2.2 Summary information and contact details

The submission should provide a summary of the treatment, target pest(s) and commodity(ies) (see Appendix 1). Where a treatment is intended to be of relevance to an existing or proposed ISPM, this should be stated in the summary. The NPPO or RPPO should designate a person to be responsible for the submission and their contact details should be provided.

2.3 Description of the phytosanitary treatment

The submission should contain a description of the treatment, including the type of treatment, treatment schedule and conditions associated with the treatment (for example, duration, temperature, active ingredient and formulation, dose, delivery method and, where appropriate, pre/post handling conditions).

2.4 Treatment targets

The targets of the treatment should be stated, including:

- the identity of the target pest(s) (taxonomic classification including strains, biotypes and, where appropriate, life stage(s))
- the identity of the commodity or regulated article for which the treatment is proposed, may include where appropriate:
  - taxonomic classification
  - description of commodity
  - state of preservation/processing or maturity (e.g. fruit, plants for planting, part of plant, wood)
  - cultivar or variety
  - description of regulated article (e.g. ship, container, soil, machinery, wood).

2.5 Efficacy data in support of the submission

The source of all efficacy data provided in the submission (published or unpublished) should be cited.

2.5.1 Efficacy data on the target pest(s) under laboratory or controlled experiments

The pest life-cycle stage for which the treatment is proposed should be specified. Usually, the most resistant stage of the pest(s) is the stage for which a treatment is proposed and established. However, practical considerations should be considered, as well as pest control strategies aimed at exploiting vulnerable or specific stages of a pest.

If efficacy data is submitted for a life-cycle stage that is not considered to be the most resistant, rationale for this (e.g. a summary of the appropriate pest control strategy) should be provided. The efficacy data provided should specify the level of confidence supporting efficacy claims made for treatment of the specified life-cycle stage.

Where possible, data should be presented on how the effective dose/treatment was determined to demonstrate the range of efficacy of the proposed treatment (e.g. dose/efficacy curves). Treatments can only be adopted for the conditions under which they were tested. Additional information should be provided to support any extrapolation if the scope of a treatment is to be extended (e.g. extending the range of temperatures or the inclusion of other varieties).

The data should include detailed information on the following elements:

- identity of the pest to the level appropriate (e.g. strain, biotype, physiological race and life stage, laboratory or field strain), including conditions under which they are cultured/reared.
- biological traits of the pest relevant to the treatment (e.g. viability, genetic variability, weight, developmental time, fecundity, freedom from disease or parasites)
- commodity type/cultivar (where varietal differences impact on treatment efficacy, data should be provided for all varieties under consideration)
- conditions of commodity, for example:
  - whether the commodity was free from disease or pesticide residue
  - size, shape, weight, stage of maturity, quality, etc.
  - infested at a susceptible stage.
- method of natural/artificial infestation
- level of confidence provided by the laboratory testing, method of statistical analysis, and the data supporting that calculation (e.g. number of subjects treated, number of replicate tests, controls)
- experimental design (e.g. randomized complete block design)
- experimental conditions (e.g. temperature, relative humidity, diurnal cycle)
- monitoring of critical parameters (e.g. dose, temperature, relative humidity)
- how the effectiveness of the treatment was determined (e.g. mortality, sterility).

The data may also include detailed information where required on:

- determination of most tolerant species/life stage
- determination of efficacy over a range of critical parameters, such as exposure time, dose, temperature, humidity and water content.

2.5.2 Efficacy data on the target pest(s) under practical conditions.

Data may be presented from preliminary tests to refine the treatment schedule to establish the effective dose (e.g. temperature, chemical, irradiation) under practical conditions.

In some cases the method of achieving the effective dose will be different from the method established under laboratory conditions. Data should be provided that supports any extrapolation of laboratory results.

Where treatment specifications differ in practical trials, the test protocol and the number of subjects treated should be indicated.

The same data requirements as listed in section 2.5.1 should also be provided for these tests. Other data which is required is listed below:

- factors that affect the performance of the treatment (packaging, packing method, stacking, timing of treatments (pre/post packaging or processing, in transit, on arrival)). The

circumstances of the treatment should be stated, for example the efficacy of a treatment may be affected by packaging and data should be provided to support all the circumstances that are applicable.

- monitoring of critical parameters (dose, temperature, relative humidity). For example:
  - the number and placement of gas sampling lines (fumigation)
  - the number and placement of temperature/humidity sensors.

In addition, any special procedures that affect the success of the treatment (e.g. to maintain the quality of the commodity) should also be included.

2.6 Information on technical and commercial feasibility

Information should be provided to support the proposed phytosanitary treatment including such items as:

- feasibility of carrying out the proposed phytosanitary treatment at a global level (includes ease of use, risks to operators, technical complexity)
- extent of existing use by NPPOs
- availability of expertise needed to apply the proposed phytosanitary treatment globally
- versatility of the proposed phytosanitary treatment (e.g. application to a wide range of countries/pests/commodities)
- the degree to which the proposed phytosanitary treatment complements other treatments or procedures (e.g. potential for the treatment to be used as part of a systems approach for one pest or to complement treatments for other pests)
- feasibility of having the proposed phytosanitary treatment accepted at a global level
- consideration of potential non-target effects.

3. Evaluation of Submissions

The Technical Panel on Phytosanitary Treatments will evaluate the submissions for their suitability of proposed treatments for inclusion in the ISPM on phytosanitary treatments [under development] and the treatment database on the International Phytosanitary Portal (IPP, https://www.ippc.int). See Appendix 2 for guidance on the evaluation process.

APPENDIX 1

COVER PAGE FOR A SUBMISSION OF A PHYTOSANITARY TREATMENT

The following summary information should be provided (see section 2.2). This cover page is designed to assist the evaluation process. The information as required in sections 2.3 to 2.6 should be appended to this cover page. Text in brackets is given for explanatory purposes.

Proposed name of treatment:

☐ Indicate ISPM number in the box if submission is applicable to an ISPM

Name of NPPO or RPPO:	
Name of person responsible for the treatment:	
Position and/or title:	
Mailing address:	
Phone:	
Fax:	
Email:	

Treatment description

Treatment name (provide enough detail to identify the treatment; for example, cold treatment of navel oranges for Mediterranean fruit fly):

Treatment type (for example, chemical, irradiation, heat, cold):

Target commodity(ies)/regulated article(s):

Target pest(s):

Schedule (include brief description such as active ingredient, dose, time and temperature):

Reason for submission: (describe why the standard is needed; where a treatment is widely used, include the countries that approve it)

Send submissions to:
E-mail: ippc@fao.org **Fax:** (+39) 06 5705 4819
Mail: IPPC Secretariat (AGPP), Food and Agriculture Organization of the UN,
Viale delle Terme di Caracalla, 00100 Rome, Italy

APPENDIX 2

OPERATIONAL PROCEDURES FOR PRIORITIZING AND EVALUATING SUBMITTED INFORMATION ON PHYTOSANITARY TREATMENTS

1. Priorities

Factors for determining priorities include:

- use of the proposed phytosanitary treatment as an alternative treatment to methyl bromide
- value of trade affected by proposed phytosanitary treatment
- relevance and value to a standard under development requiring phytosanitary treatment(s)
- frequency with which a proposed phytosanitary treatment is linked to a trade issue (e.g. disputes or need for repeated bilateral discussions)
- relevance and utility to developing countries
- emergency need for the proposed phytosanitary treatment
- long term benefits of the proposed phytosanitary treatment (e.g. chemicals likely to be banned or withdrawn would be low priority)
- issues associated with deferring or rejecting the proposed phytosanitary treatment.

2. Evaluations of Submissions

Submissions will be considered by the Technical Panel on Phytosanitary Treatments only when the following information is complete (see section 2):

- summary information and contact details
- description of the treatment
- treatment targets
- efficacy data in support of the submission
- information on technical and commercial feasibility.

The Technical Panel on Phytosanitary Treatments will exercise due respect for confidentiality where sensitive information is provided by the applicant.

In evaluating submissions, the Technical Panel on Phytosanitary Treatments will consider the following criteria:

- the experience or expertise in the subject area of the laboratory, organization and/or scientist(s) involved in producing the data
- whether the data was published. More weight may be given to data that was published in international peer-reviewed journals.
- the availability of experts to evaluate the proposed phytosanitary treatment
- whether researchers utilized a quality assurance or accreditation program in the development and/or testing of the proposed phytosanitary treatment.

Treatments will only be approved for the conditions under which they were tested, unless data is presented to support extrapolation (for example to apply the treatment to a range of pest species or commodities).

3. Outcome of Evaluation

Once a submission has been evaluated and the treatment has been found to meet the criteria for adoption internationally, it will be recommended as an international treatment. After adoption by the ICPM, the treatment will be incorporated into the ISPM on phytosanitary treatments [under development] and the treatment database on the International Phytosanitary Portal (IPP, http://www.ippc.int).

If the submission fails to meet the criteria for adoption internationally, the reason(s) will be communicated to the contact identified on the submission. There may be a recommendation to provide additional information or to initiate further work (e.g. research, field testing, analysis).